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| 10/505,304  | 07/11/2005  | Ian Revie            | 1781-0010                           | 6005                   |
| 28078 7590 12/18/2008<br>MAGINOT, MOORE & BECK, LLP<br>CHASE TOWER<br>111 MONUMENT CIRCLE<br>SUITE 3250<br>INDIANAPOLIS, IN 46204 |             |                      | EXAMINER<br>KASZTEJNA, MATTHEW JOHN |                        |
|   |             |                      | ART UNIT<br>3739                    | PAPER NUMBER           |
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/505,304  
Filing Date: July 11, 2005  
Appellant(s): REVIE ET AL.

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Paul J. Maginot  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed September 22, 2008 appealing from the Office action mailed April 22, 2008.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

|           |                     |         |
|-----------|---------------------|---------|
| 6,478,802 | Kienzle, III et al. | 11-2002 |
| 6,272,370 | Gillies et al.      | 8-2001  |
| 6,203,493 | Ben-Haim            | 3-2001  |

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claim 2-6, 8, 12-15, 19-20, 22-23 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle, III et al. (U.S. Patent No. 6,478,802) in view of Gillies et al. (U.S. Patent No. 6,272,370).

**In regard to claims 2-6, 8, 12-15, 19-20, 22-23,** Kienzle, III et al. disclose a surgical instrument system, which comprises: a drill bit 105 including an elongate shaft which defines a drill bit axis, the instrument bearing a plurality of markers rings arranged in a predetermined pattern, which are more reflective than the surface of the instrument (see Figs. 1-2 and Col. 4, Lines 25-43), at least two receiving devices which are spaced apart for receiving stereoscopic signals from the rings on the drill bit (see Col. 1, Lines 15-30), a data processor for analyzing the signal from the rings and generating information relating to the position and orientation of the reel drill bit relative to the receiving device (see Fig. 4), and a drive unit operable to rotate the reel drill bit about the drill bit axis (see Col. 4, Lines 1-10). Kienzle, III et al. teach that it is well known within the art of localizing devices to use an optical localizer that employs a stereoscopic camera system to view infrared light emitters or reflectors that are placed on the surgical instruments and that any arrangement of emitters that allows the

localizer to determine the pose of the drill emitter coordinate frame with sufficient accuracy may be used without departing from the instant invention. However, Kienzle, III et al. are silent with respect to a plurality of markers rings are arranged in a predetermined pattern on the surface of the shaft. Gillies et al. teach of an analogous endoscopic apparatus comprised of an elongate shaft with a plurality of MR-visible markers 6 disposed at the distal end to provide easily identifiable reference points for trackability and localization under MR imaging and X-ray fluoroscopy (see Figure 1 and col. 25, lines 39-43). The markers 6 can be formed of radioopaque materials, such as gold, platinum or tantalum, which are more reflective than the copolymer of the shaft 2 of the microcatheter 1 (see col. 25, lines 10-53). As seen in figures 2 and 4a-b, Gillies et al. teach of placing the radioopaque materials in rings around the shaft of the instrument and wherein the planes defined by the axially spaced edges of each marker 6 are parallel to one another and perpendicular to the axis of the shaft 2. **In regard to claims 25-27**, Gillies et al. teach of placing the MR-visible markers along its length, having marker placed at a proximal portion of the shaft (see Col. 13, Lines 23-30). It would have been obvious to one skilled in the art at the time the invention was made to place a plurality of marker rings around the shaft of the drill bit in the apparatus of Kienzle, III et al. in order to more accurately define the location and orientation of the shaft as it enters the body as taught by Gillies et al.

Claims 7, 16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle, III et al. (U.S. Patent No. 6,478,802) in view of Gillies et al. (U.S. Patent No. 6,272,370) in further view of Ben-Haim (U.S. Patent No. 6,203,493).

**In regard to claims 7, 16 and 24**, Kienzle, III et al. and Gillies et al. disclose a surgical instrument system, which comprises: a drill bit 105 including an elongate shaft which defines a drill bit axis, the shaft bearing a plurality of markers rings arranged in a predetermined pattern (see Figs. 1-2 and Col. 4, Lines 25-30), at least two receiving devices which are spaced apart for receiving stereoscopic signals from the rings on the drill bit (see Col. 1, Lines 15-30), a data processor for analyzing the signal from the rings and generating information relating to the position and orientation of the reel drill bit relative to the receiving device (see Fig. 4), and a drive unit operable to rotate the reel drill bit about the drill bit axis (see Col. 4, Lines 1-10). Kienzle, III et al. are silent with respect wherein the rings are marked on a sleeve which is fitted onto the instrument. Ben-Haim teaches a similar tracking device for an endoscope comprised of a sheath 20 having a plurality of sensors 22 spaced along the axis of the endoscope (see Figure 1). It would have been obvious for one of ordinary skill in the art at the time the invention was made to provide the instrument of Kienzle, III et al. and Gillies et al. with a sheath containing the markers 6, in the manner disclosed by Ben-Haim, as Ben-Haim demonstrates that sheaths containing radio-opaque markers for placement over an surgical device are well known in the art.

#### **(10) Response to Argument**

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one skilled in the art at the time the invention was made to place a plurality of marker rings around the shaft of the drill bit in the apparatus of Kienzle, III et al. in order to more accurately define the location and orientation of the shaft as it enters the body as taught by Gillies et al. Kienzle, III et al. teach that it is well known within the art of localizing devices to use an optical localizer that employs a stereoscopic camera system to view infrared light emitters or reflectors that are placed on the surgical instruments and that any arrangement of emitters that allows the localizer to determine the pose of the drill emitter coordinate frame with sufficient accuracy may be used without departing from the instant invention. The localizing emitters may comprise reflectors, spheres, visible spectrum emitters or any other suitable device well known in the art. However, Kienzle, III et al. are silent with respect to a plurality of markers rings are arranged in a predetermined pattern on the surface of the shaft. Gillies et al. teach that it is beneficial to place markers around the shaft of an instrument placed within the body to provide an image guided system during a surgical procedure. The visible markers placed along the length of the apparatus allow for easily identifiable reference points for trackability and localization during surgical procedures. Thus, placing the markers on the shaft of the drill bit of Kienzle, III et al. would allow for more accurate positioning of the drill and drill guide and calculating the pose thereof, as the drill is inserted into a patient's body. Applicant also states that Gillies would, at best, suggest

placing the markers along the length of Kienzle's housing. Examiner disagrees. As stated above, the markers are placed along the working length of guide or push wire 4, to enable a user to localize and track the apparatus as it is placed within the body (see Figs. 1-2). Thus, Gillies teach to place visible markers around a working shaft of an instrument that is inserted into a patient, corresponding to the drill bit 105 of Kienzle which is the working shaft of the apparatus and is inserted into the patient during a surgical procedure.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a plurality of marker rings located on the drill bit, wherein they remain *visible* to the receiving devices outside the bone tissue) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant also states that it would not have been obvious to one skilled in the art to place a plurality of markers around the shaft of the drill bit in the apparatus of Kienzle based on the teaching of Gillies as the marker would likely wear off. Examiner disagrees. Applicant states that there are no "wearing issues" with respect to the use of Gillies' cerebral catheters. However, it is well known in the art that the gold, platinum or tantalum MR-visible markers 6 should be fixedly secured to the shaft so as not to become dislodged within the patient during use. Furthermore, Gillies discloses that the markers may be placed along the entire length of the shaft as the MR visibility is



variably adjustable based on requirements related to degree of signal loss for device localization and positioning, enhancement along the shaft of the device, enhancement around the body of the device, visibility of the proximal and distal ends of the device, degree of increased background noise associated with the device movement, and other factors which either increase or suppress background noise associated with the device (see Col. 23, Lines 37-45). Thus, the markers are not placed on the distal most end of the shaft (i.e. the exposed surface of the drill bit) and are not susceptible to significant friction caused by the drill bit. As seen in Figure 1 of Gillies, the markers 6 are located along the length of the shaft and assist in tracking the apparatus during insertion within the body as discussed above.

Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., permanent marker rings) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Art Unit: 3739

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Matthew J Kasztejna/  
Examiner, Art Unit 3739  
12/11/08

Conferees:

/Linda C Dvorak/

Supervisory Patent Examiner, Art Unit 3739

/Angela D Sykes/

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